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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/791,974
Filing Date: March 03, 2004
Appellant(s): PICKUP ET AL.

Walter W. Karnstein
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 18, 2008 appealing from the Office action mailed April 17, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,179,947	MEYERSON et al	01-1993
5,480,062	ROGERS et al	01-1996
5,860,957	JACOBSEN et al	01-1999
6,048,337	SVEDMAN	04-2000
6,325,475	HAYES et al	12-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 83-85, 87-89, 91-95, 98, 99, 102,105-107, 118, 123, 126, 131, 136, 140, 141 and 183-185 are rejected under 35 U.S.C. 102(b) as being anticipated by Svedman (U.S. Patent No. 6,048,337)

With respect to **claim 83:** Svedman teaches a method of administering a bioactive composition to a subject, the method comprising: applying to a cutaneous surface of the subject a jet dispenser comprising a container in the form of drug cell 175 holding the bioactive composition (Fig. 79, Col. 35, lines 46-48). The method also comprises the step of dispensing the bioactive

composition in droplets from the dispenser through at least one orifice in the form of an array of nozzles toward the cutaneous surface such that the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface. (Col. 35, lines 51-63) Examiner's position is based upon Svedman's teaching regarding the technique for creating a delivery site on the cutaneous surface prior to dispensing the composition. Specifically, throughout the disclosure Svedman teaches that the technique for creating the de-epithelialized site for delivery of the composition comprises creating a blister and then removing the blister roof and replacing the roof with the orifice of the dispenser. The dispenser orifice is elevated with respect to the cutaneous surface and the base of the delivery site directly below is recessed with respect to the same cutaneous surface. Therefore, there is necessarily open space, or air, between the orifice where the droplets of composition exit and the cutaneous surface containing the de-epithelialized delivery site. The droplets enter this open air space or gap upon exiting the at least one orifice, becoming airborne in the open space between the plane of the orifices and the base of the delivery site, and remain airborne until they exit that space, i.e. the droplet comes in contact with the cutaneous surface of the delivery site. With regard to the limitation "retaining the bioactive composition in prolonged contact with the cutaneous surface", appellant discloses no quantitative time interval range for "prolonged contact with the cutaneous surface" and only discloses that this prolonged contact is accomplished by attaching the claimed device to the cutaneous surface. Since Svedman teaches that the dispenser is attached to the cutaneous surface of a user via suction, this limitation flows inherently and necessarily from the teachings of Svedman. (Abstract)

With respect to **claim 84:** Svedman teaches an embodiment in Fig. 70 in which the step of retaining the bioactive composition in prolonged contact with the cutaneous surface comprises

dispensing the bioactive composition on to a patch 121 that is retained on the cutaneous surface. (Col. 31, lines 16-21)

With respect to **claim 85:** The patch 121 is an adhesive dermal patch having adhesive layer 125 that is applied to the cutaneous surface prior to dispensing the bioactive composition from the dispenser. (Col. 32, lines 56-61)

With respect to **claim 87:** Svedman teaches a method wherein retaining the bioactive composition in prolonged contact with the cutaneous surface comprises providing a seal between the dispenser and cutaneous surface via application of suction to form a substantially sealed chamber between the dispenser and the cutaneous surface, and retaining the dispenser in prolonged contact with the seal. (Abstract)

With respect to **claim 88:** Svedman teaches repeatedly dispensing the bioactive composition toward the cutaneous surface inasmuch as Svedman teaches that the patch 121 is in registration with the cutaneous surface for several days and teaches that the patch remains in place "for a subsequent procedure", interpreted herein as a subsequent dispensation of said drug. (Col. 32, lines 62-66)

With respect to **claim 89:** Svedman teaches the step of filling a drug reservoir with liquid drug and a drug insertion port 685 in association with the embodiment of Fig.29, upon which the embodiment of Figs 63-69 is based. Thus Svedman teaches the step of resupplying the dispenser with the bioactive substance. (Col. 21, lines 27-33, Col. 22, lines 12-17)

With respect to **claim 91:** Svedman teaches a method of administering a bioactive composition to a subject, the method comprising: applying a cutaneous patch 121 to the skin of the subject (Fig. 63, Col. 31, lines 13-16); and dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of site 8 (the site to which patch 121 is ultimately delivered) or the patch 121 in the form of aperture 6. (Figs. 63,65,66, Col. 31, lines 12-15)

With respect to **claim 92:** Svedman is considered herein to teach dispensing the bioactive composition to the patch at intervals inasmuch as Svedman teaches that the patch 121 is in registration with the cutaneous surface for several days and teaches that the patch remains in place "for a subsequent procedure", interpreted herein as a subsequent dispensation of said drug. (Col. 32, lines 62-66) The limitation "to provide sustained dosages of the bioactive composition from the patch to the subject" constitutes functional language that is given little patentable weight herein.

With respect to **claim 93:** The intervals are preselected intervals inasmuch as the delivery of drug dosages is controlled. (Col. 8, lines 21-34)

With respect to **claim 94:** The method taught by Svedman further comprises controlling the rate of drug delivery to stabilize a measured parameter at a desired level, i.e. dispensing the bioactive composition from the dispenser to the patch 121 when an amount of the bioactive composition in the patch rises above or falls below a desired level as detected by biosensor 168. (Col. 36, lines 1-8)

With respect to **claim 95:** Svedman teaches an embodiment in Fig. 53 wherein the step of dispensing further comprises dispensing a second substance from a second compartment 71 from the dispenser to the patch 121 (Col. 28, lines 15-27). Svedman teaches an embodiment in Fig. 80 wherein drug cell 145 contains a drug mixed with a hydrogel prior to dispensing.

With respect to **claim 98:** The method taught by Svedman further comprises containing said bioactive composition with a container portion, e.g. collection chamber 160 of said inkjet dispenser prior to said dispensing. (Fig. 78, Col. 35, lines 27-29)

With respect to **claim 99:** The method taught by Svedman further comprises filling said container portion 160 prior to any dispensation of drug, thus since Svedman teaches repeated administrations of said drug, Svedman also teaches refilling said container portion with said bioactive composition. (Fig. 78, Col. 35, lines 27-29)

With respect to **claim 102:** The dispensing step taught by Svedman comprises using a thermal droplet jet dispenser. (Col. 34, lines 54-64)

With respect to **claim 105:** The inkjet dispenser used in said dispensing comprises a thermal inkjet dispenser, wherein dispensing the bioactive composition from the thermal inkjet dispenser comprises receiving the bioactive composition into a feed chamber 160 from a reservoir 145 in the dispenser (Col. 35, lines 25-32). The method further comprises the step of flowing the bioactive composition from the feed chamber 160 into a vaporization chamber within pump 177 in the dispenser (Col. 35, lines 54-58). The limitations "energizing a firing resistor in the

vaporization chamber"and "ejecting the bioactive composition as a droplet from the vaporization chamber" flow inherently and necessarily from Svedman's teachings of a thermal jet droplet dispenser having electrical heating element 179 (Col. 35, lines 58-63, Col. 36, lines 11-15).

With respect to **claim 106:** The method of the combined teaching of Svedman and Hayes teaches a piezoelectric inkjet dispenser, The limitations "dispensing the bioactive composition from the piezoelectric inkjet dispenser comprises receiving the bioactive composition into a piezoelectric chamber from a storage chamber in the dispenser"," passing an electric current through a piezoelectric member in the chamber, thereby expanding the piezoelectric member" and "expelling the bioactive composition as a droplet from the vaporization chamber" flow inherently and necessarily from the device fairly suggested by Svedman as supported by Hayes, which fairly suggests a piezoelectric inkjet dispenser.

With respect to **claim 107:** The method of the combined teaching of Svedman and Hayes teaches a step of dispensing comprises a silicon electrostatic actuated inkjet dispenser as stated *supra* with respect to claim 104.

With respect to **claim 118:** Svedman teaches monitoring a physical parameter of the subject via monitoring of the value of the parameter in a sample of exudates from exposed dermis at the injection site on the user (Col 36, lines 1-6); and in response to said monitoring, controlling the rate of drug delivery to stabilize the measured parameter at a desired level, i.e. adjusting said dispensing. (Col 36, lines 1-6)

With respect to **claim 123:** The monitoring comprises using a monitor portion in the form of biosensor 168 of the jet dispenser. (Col. 35, lines 34-42)

With respect to **claim 126:** Svedman teaches monitoring a physical parameter of the subject via monitoring of the value of the parameter in a sample of exudates from exposed dermis at the injection site on the user (Col 36, lines 1-6); and in response to said monitoring, controlling the rate of drug delivery to stabilize the measured parameter at a desired level, i.e. adjusting said dispensing. (Col 36, lines 1-6)

With respect to **claim 131:** The monitoring comprises using a monitor portion in the form of biosensor 168 of the jet dispenser. (Col. 35, lines 34-42)

With respect to **claim 136:** Svedman teaches applying a bioactive composition attracting agent in the form of patch 121 to a treatment location on the cutaneous surface of the subject in the form of an iontophoresis process; pulling the bioactive composition toward said agent by applying a voltage of appropriate polarity between a first electrode 187 within cell 145 where the drug is located, and second electrode 188 located adjacent the skin peripheral to the de-epthelialized site (i.e. the injection site). The difference in voltage has an associated mechanical force that drives the drug from cell 145 toward the injection site for absorption. The drug then penetrates said agent 121 with the bioactive composition to treat the treatment location with the bioactive composition. (Col. 36, lines 53-62)

With respect to **claim 140:** Svedman teaches manually triggering an activation device 127 after said applying and before said dispensing via patch 121, with said dispensing occurring in

response to said triggering, specifically actuator 127 displaces support ring and with it patch 121 in a direction that is at a right angle to base 3, which is depicted in Fig. 63 as the outermost housing surrounding the entire dispenser. (Col. 31, lines 44-48, Col. 32, lines 51-56)

With respect to **claim 141:** Svedman teaches manually triggering an activation device 127 after said applying and before said dispensing via patch 121, with said dispensing occurring in response to said triggering, specifically actuator 127 displaces support ring and with it patch 121 in a direction that is at a right angle to base 3, which is depicted in Fig. 63 as the outermost housing surrounding the entire dispenser. (Col. 31, lines 44-48, Col. 32, lines 51-56)

With respect to **claim 183:** The step of dispensing taught by Svedman is performed with the orifice spaced from and directly above a face of site 8 (the site to which patch 121 is ultimately delivered) or the patch 121 in the form of aperture 6. (Figs. 63,65,66, Col. 31, lines 12-15)

With respect to **claim 184:** The dispensing step of the method of Svedman is performed such that the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface. (Col. 35, lines 51-63) Examiner's position is based upon Svedman's teaching regarding the technique for creating a delivery site on the cutaneous surface prior to dispensing the composition. Specifically, throughout the disclosure Svedman teaches that the technique for creating the de-epithelialized site for delivery of the composition comprises creating a blister and then removing the blister roof and replacing the roof with the orifice of the dispenser. The dispenser orifice is elevated with respect to the cutaneous surface and the base of the delivery site directly below is recessed with respect to the same cutaneous surface. Therefore, there is necessarily open

space, or air, between the orifice where the droplets of composition exit and the cutaneous surface containing the de-epithelialized delivery site. The droplets enter this open air space or gap upon exiting the at least one orifice, becoming airborne in the open space between the plane of the orifices and the base of the delivery site, and remain airborne until they exit that space, i.e. the droplet comes in contact with the cutaneous surface of the delivery site.

With respect to **claim 185:** The method also includes the step of dispensing the bioactive composition as droplets from the dispenser that travel from the at least one orifice in the form of an array of nozzles toward the cutaneous surface 8 (or ultimately, patch 121) across an airgap that extends directly from the orifice to the patch 121. (Col. 35, lines 51-63) Examiner's position is based upon Svedman's teaching regarding the technique for creating a delivery site on the cutaneous surface prior to dispensing the composition. Specifically, throughout the disclosure Svedman teaches that the technique for creating the de-epithelialized site for delivery of the composition comprises creating a blister and then removing the blister roof and replacing the roof with the orifice of the dispenser. The dispenser orifice is elevated with respect to the cutaneous surface and the base of the delivery site directly below is recessed with respect to the same cutaneous surface. Therefore, there is necessarily open space, or air, between the orifice where the droplets of composition exit and the cutaneous surface containing the de-epithelialized delivery site. The droplets enter this open air space or gap upon exiting the at least one orifice, becoming airborne in the open space between the plane of the orifices and the base of the delivery site, and remain airborne until they exit that space, i.e. the droplet comes in contact with the cutaneous surface of the delivery site.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 86, 96, 97,119, 120, 127, 128 and 148-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('337).

With respect to **claim 86:** The patch 121 comprises a selectively removable cover in the form of conventional patch 135. (Col. 32, lines 51-61) The removable cover 135 is subsequently replaced on the patch. The limitation "to improve retention of the bioactive composition in the patch" constitutes functional language that is given little patentable weight herein.

Svedman does not explicitly teach that cover 121 is removed prior to dispensing the bioactive composition into the patch. However, Svedman teaches that patch 121 can be used alone or with cover 135 to deliver said drug. Therefore it would be obvious to one of ordinary skill in the art to modify the device of Svedman such that the cover 135 is removed prior to dispensing the bioactive composition into patch 121 with a reasonable expectation of success, as the patch 121 can still perform the intended function of delivering the drug without the cover 135 present.

With respect to **claim 96:** Svedman does not teach a method wherein said mixing occurs between said orifice and said patch. However, Svedman teaches collection chamber 160

wherein liquid samples can be collected and drug is channeled from the reservoir(s) e.g. cell 145 or compartments 71, thus it would be obvious to one of ordinary skill in the art to modify the device of Svedman such that the drugs in said compartments 71 are mixed between the orifice and the patch 121 with a reasonable expectation of success as there are only a finite number of points at which the drugs can be mixed. If there is a design need or a market pressure to solve a problem, and there are a finite number of identified, predictable solutions, a person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007)

With respect to **claim 97:** Svedman does not teach a method wherein said mixing occurs within said patch. However, Svedman teaches collection chamber 160 wherein liquid samples can be collected and drug is channeled from the reservoir(s) e.g. cell 145 or compartments 71, thus it would be obvious to one of ordinary skill in the art to modify the device of Svedman such that the drugs in said compartments 71 are mixed between the orifice and the patch 121 with a reasonable expectation of success as there are only a finite number of points at which the drugs can be mixed. If there is a design need or a market pressure to solve a problem, and there are a finite number of identified, predictable solutions, a person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007)

With respect to **claim 119:** Svedman does not teach that the physical parameter comprises heartbeats. However, since Svedman teaches that the drug comprises pain medication, which

slows a human heart rate and teaches controlling drug delivery rate to maintain said parameter at a desired level, it would be obvious to one of ordinary skill in the art to modify the method of Svedman such that the physical parameter monitored comprises heartbeats. (Col. 37, lines 46-49, Col. 36, lines 1-6)

With respect to **claim 120:** Svedman does not teach that the physical parameter comprises breathing. Examiner is interpreting the term "breathing" as equivalent to breathing rate, as it is believed that this is what is intended and is what is disclosed. However, since Svedman teaches that the drug comprises pain medication, which slows breathing rate and teaches controlling drug delivery rate to maintain said parameter at a desired level, it would be obvious to one of ordinary skill in the art to modify the method of Svedman such that the physical parameter monitored comprises heartbeats. (Col. 37, lines 46-49, Col. 36, lines 1-6)

With respect to **claim 127:** Svedman does not teach that the physical parameter comprises heartbeats. However, since Svedman teaches that the drug comprises pain medication, which slows a human heart rate and teaches controlling drug delivery rate to maintain said parameter at a desired level, it would be obvious to one of ordinary skill in the art to modify the method of Svedman such that the physical parameter monitored comprises heartbeats. (Col. 37, lines 46-49, Col. 36, lines 1-6)

With respect to **claim 128:** Svedman does not teach that the physical parameter comprises breathing. Examiner is interpreting the term "breathing" as equivalent to breathing rate, as it is believed that this is what is intended and is what is disclosed. However, since Svedman teaches that the drug comprises pain medication, which slows breathing rate and teaches controlling

drug delivery rate to maintain said parameter at a desired level, it would be obvious to one of ordinary skill in the art to modify the method of Svedman such that the physical parameter monitored comprises heartbeats. (Col. 37, lines 46-49, Col. 36, lines 1-6)

With respect to **claim 148:** Svedman does not teach storing the bioactive composition in a collapsible bladder. However a pouch is simply another container and accomplishes the identical result of confining a drug dosage until use to the drug cell 145, therefore it would be obvious with a reasonable expectation of success to modify the method of Svedman such that the drug is stored in a collapsible bladder to accomplish the result of holding the bioactive composition in a sterile environment prior to use. The method fairly suggested by Svedman teaches conveying the bioactive composition from a container (drug cell 145) to the jet dispenser.

With respect to **claim 149:** In the embodiment taught by Svedman in Fig. 90, said step of conveying from a container 262 comprises conveying the bioactive composition through suction tubing 15. (Col. 38, lines 5-8)

With respect to **claim 150:** Svedman does not teach storing the bioactive composition in a collapsible bladder. However a pouch is simply another container and accomplishes the identical result of confining a drug dosage until use to the drug cell 145, therefore it would be obvious with a reasonable expectation of success to modify the method of Svedman such that the drug is stored in a collapsible bladder to accomplish the result of holding the bioactive composition in a sterile environment prior to use. The method fairly suggested by Svedman

teaches conveying the bioactive composition from a container (drug cell 145) to the jet dispenser.

Claims 90 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('337) in view of Rogers (U.S. Patent No. 5,480,062).

With respect to **claim 90:** Svedman teaches that resupplying the dispenser comprises injecting the drug from a separate container and thus does not teach replacing a container in the dispenser. Rogers teaches a vacuum operated medicine dispensing device wherein a plurality of storage containers 210 are sized to receive refill cartridges 212 of medication. Rogers teaches that this allows for the provision of a backup supply of medication, therefore it would be obvious to one of ordinary skill in the art to modify the device of Svedman such that resupplying the dispenser comprises replacing a container in the reservoir (e.g. reservoir 660 in Figs. 28,29) of said dispenser as taught by Rogers to provide a backup supply of drug to ensure timely administration of said drug. ('062, Fig. 2, Col. 7, lines 24-33)

With respect to **claim 100:** A method according to claim 99 further comprising

Svedman does not teach that container 160 is removed and thus does not teach the step of removing said container portion from the inkjet dispenser prior to said refilling, and after said refilling, replacing said container portion for further dispensing. Rogers teaches a vacuum operated medicine dispensing device wherein a plurality of storage containers 210 are sized to receive refill cartridges 212 of medication. Rogers teaches that this allows for the provision of a backup supply of medication, therefore it would be obvious to one of ordinary skill in the art to modify the device of Svedman such that resupplying the dispenser comprises replacing a

container in the reservoir (e.g. collection chamber 160 in Figs. 28,29) of said dispenser as taught by Rogers to provide a backup supply of drug to ensure timely administration of said drug. ('062, Fig. 2, Col. 7, lines 24-33)

Claims 103 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('337) in view of Hayes et al (U.S. Patent No. 6,325,475)

With respect to **claim 103:** Svedman teaches a thermal droplet jet dispenser, but does not teach that the step of dispensing comprises using a piezoelectric droplet jet dispenser. Hayes teaches a jet dispenser for administering airborne materials into a user's nose that utilizes ink-jet technology. Hayes teaches that the transducer in the ink jet device can be piezoelectric or electromechanical (as is taught by Svedman in Col. 35, lines 58-63 and Col. 36, lines 10-15). ('475, Col. 7, lines 29-37) Since Hayes teaches that piezoelectric and electromechanical droplet jet dispensers such as thermal droplet jet dispensers are equivalent methods of creating and dispensing droplets of a drug, it would be obvious to one of ordinary skill in the art to utilize any of piezoelectric, thermal or silicon electrostatic transducers as taught by Hayes. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

With respect to **claim 104:** Svedman teaches a thermal droplet jet dispenser, but does not teach that the step of dispensing comprises using a silicon electrostatic actuated droplet jet dispenser. Hayes teaches a jet dispenser for administering airborne materials into a user's nose that utilizes ink-jet technology. Hayes teaches that the transducer in the ink jet device can be

piezoelectric or electromechanical (as is taught by Svedman in Col. 35, lines 58-63 and Col. 36, lines 10-15). ('475, Col. 7, lines 29-37) Silicon electrostatic actuated droplet dispensers are interpreted herein as an example of an electromechanical dispenser, given their nature of operation as disclosed by appellant:

"The ink ejection mechanism 316 includes a silicon substrate 322 that contains for each nozzle 320 an individually energizable thin film firing resistor 324, each located generally behind an associated single nozzle 320. The firing resistors 324 act as ohmic heaters (electric heaters) when selectively energized by one or more enabling signals or firing pulses 325, which are delivered from a controller 326 through conductors (omitted for clarity) carried by the polymer tape 318." (Specification, [72])

The electric ohmic heaters then heat the drug passing through nozzles 320, which is the mechanical aspect of the silicon-actuated dispenser. Since Hayes teaches that piezoelectric and electromechanical droplet jet dispensers are equivalent methods of creating and dispensing droplets of a drug, it would be obvious to one of ordinary skill in the art to utilize any of piezoelectric, thermal or silicon electrostatic transducers as taught by Hayes. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

Claims 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('337) in view of Jacobsen (U.S. Patent No. 5,860,957).

With respect to **claims 108,109:** Svedman does not teach any of the limitations of claim 108 or 109. Jacobsen teaches that a drug is specifically selected by name via the ability of device 20 to read a label on a drug storage container as it is inserted. An external host interface 48 obtains

and stores data via a wireless infrared reading device from a computer having microprocessor 40, said data including user ID, drug ID, dose and usage information. Wireless interface 48 then uses said data to monitor a patient's physiological status in tandem with sensors, this circuit also thus being capable of responding to the data by administering the appropriate dosage via device 20 according to the stored schedule data. (Col. 7, lines 24-38) Since Svedman also teaches monitoring a physical parameter in the instant method, it would be obvious to one of ordinary skill in the art to modify the method of Svedman to include the steps set forth in claim 108 and claim 109 as taught by Jacobsen with a reasonable expectation of success to maintain the parameter value at the desired level.

Claims 124, 125, 132 and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('337) in view of Meyerson et al (U.S. Patent No. 5,179,947).

With respect to **claim 124:** Svedman teaches that the monitor portion 168 comprises a sensor that is appropriate for the parameter, but does not explicitly teach that the monitor portion comprises a mechanical sensor. Meyerson teaches an acceleration-sensitive cardiac pacemaker that employs an accelerometer (mechanical sensor) to monitor the heart rate of the user. Meyerson teaches that an accelerometer sensor is able to detect a level of constant pressure, not just changes in pressure and is sensitive to changes in activity level of the user, therefore it would be obvious to one of ordinary skill in the art to employ an accelerometer as the monitor portion taught by Svedman so as to render the device capable of detecting both a change in activity level of the user by measuring heart rate, and also capable of detecting a level which is sustainable and acceptable for the user as taught by Meyerson.

With respect to **claim 125:** Svedman does not teach a mechanical sensor or that said sensor comprises an accelerometer. Meyerson teaches an acceleration-sensitive cardiac pacemaker that employs an accelerometer (mechanical sensor) to monitor the heart rate of the user. Meyerson teaches that an accelerometer sensor is able to detect a level of constant pressure, not just changes in pressure and is sensitive to changes in activity level of the user, therefore it would be obvious to one of ordinary skill in the art to employ an accelerometer as the sensor of the device taught by Svedman so as to render the device capable of detecting both a change in activity level of the user by measuring heart rate, and also capable of detecting a level which is sustainable and acceptable for the user as taught by Meyerson.

With respect to **claim 132:** Svedman teaches that the monitor portion 168 comprises a sensor that is appropriate for the parameter, but does not explicitly teach that the monitor portion comprises a mechanical sensor. Meyerson teaches an acceleration-sensitive cardiac pacemaker that employs an accelerometer (mechanical sensor) to monitor the heart rate of the user. Meyerson teaches that an accelerometer sensor is able to detect a level of constant pressure, not just changes in pressure and is sensitive to changes in activity level of the user, therefore it would be obvious to one of ordinary skill in the art to employ an accelerometer as the monitor portion taught by Svedman so as to render the device capable of detecting both a change in activity level of the user by measuring heart rate, and also capable of detecting a level which is sustainable and acceptable for the user as taught by Meyerson.

With respect to **claim 133:** Svedman does not teach a mechanical sensor or that said sensor comprises an accelerometer. Meyerson teaches an acceleration-sensitive cardiac pacemaker that employs an accelerometer (mechanical sensor) to monitor the heart rate of the user.

Meyerson teaches that an accelerometer sensor is able to detect a level of constant pressure, not just changes in pressure and is sensitive to changes in activity level of the user, therefore it would be obvious to one of ordinary skill in the art to employ an accelerometer as the sensor of the device taught by Svedman so as to render the device capable of detecting both a change in activity level of the user by measuring heart rate, and also capable of detecting a level which is sustainable and acceptable for the user as taught by Meyerson.

(10) Response to Argument

Appellant's arguments filed August 18, 2008 have been fully considered but they are not persuasive.

With respect to arguments regarding claim 83: Appellant argues, beginning on page 15 of the Brief, that Svedman does not disclose the step of dispensing a bioactive composition such that the composition becomes airborne upon leaving the at least one orifice. This is not persuasive because Svedman discloses in Col. 35, lines 54-63 that the pump 177 of Fig. 79 is a thermal droplet generator with an array of nozzles (at least one orifice) that dispenses a drug (bioactive composition) in droplets from the dispenser, pump 177, through at least one orifice (the array of nozzles) toward the cutaneous surface, specifically toward drug cell 175 where the drug will subsequently be administered to the cutaneous surface. ('337, Col. 35, lines 50-63) It is examiner's position that when droplets are formed, air is also necessarily present, especially since the droplets are conveyed toward the drug cell 175, thus they are airborne, as air is necessarily present in the conduit. Therefore Svedman anticipates this limitation. As to the argument that Svedman does not disclose placement of a micro-pump over a de-epithelialized site, such argument is moot in view of examiner's clarification *supra*. It does not matter whether the pump is over the site, as such a limitation is neither claimed nor necessary for the device of

Svedman to anticipate the limitations of claim 83. As to appellant's apparent argument on page 18 that exmainer modified the embodiemtn of Fig. 79 of Svedman to meet the limitations of claim 83, this argument ios addressed by examiner's response thus far regarding claim 83; a single embodiment, that of Fig, 79, anticipates all of the limitations of claim 83; no modification was suggested by examiner nor is modification of the embodiment of Fig. 79 necessary.

With respect to arguments regarding claim 91: Appellant argues that Svedman does not anticipate claim 91 because Svedman does not disclose any active mechanisms for dispensing a drug to a patch. The embodiment of Fig. 63 of Svedman was cited against the claim. Appellant is referred to Col. 31, lines 12-15 where Svedman explicitly discloses that "the device 1 is modified in Fig. 63 to include a patch applicator 120 which is operable to apply to the area of skin following de-epithelialization while the device 1 remains in situ" The device 1 to which Svedman refers is disclosed in Figs. 34-37 and beginning on Col. 23, line 37, where Svedman discloses that "Fig. 34 shows a further device 1 for use in the transdermal delivery of a liquid drug in contact with a de-epithelialised [sic] area of skin and for initially de-epithelialising the skin by formation and subsequent disruption of a suction blister." Thus the embodiment of Fig. 63 is identical to the device 1 of Figs. 34 through 37 except for the application of a patch after de-epithelialisation. It is examiner's position therefore that the patch 121 must be present over the site prior to delivery of the drug, and therefore the drug is necessarily delivered from device 1 to the patch 121. This position is supported by Col. 33, lines 24-32 of Svedman and shown in Fig. 69. In order for the patch 121 of Fig. 69 to effect transdermal delivery, it must receive the drug from the device 1, which is physically located directly above a face of the patch, as can be seen in Figs. 65 and 68. It is also examiner's position that the orifice for delivery, aperture 6, is necessarily spaced from a face of the patch 121 in order for the drug to be able to be administered to the patch 121, rather than being trapped and or pooling at the orifice 6.

Appellant's arguments with regard to dependent claims 84-90, 92-100, 10-109, 118-120, 123-128, 131-133, 136, 140, 141, 148-150 and 183-185 have been fully considered but are not persuasive, as applicant's arguments depend entirely on arguments regarding the rejections of claims 83 and 91, which have been addressed *supra*.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Melanie J Hand/

Examiner, Art Unit 3761

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/Tatyana Zalukaeva/

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